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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,022	09/17/2003	Dennis M. Klinman	4239-66899	7954

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
09/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,022	KLINMAN ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6,8-21 and 25-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-6,8-21 AND 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 6/5/2008. The status of the claims is as follows: claims 1, 2, 4-6, 8-21, 25-32 are under current examination. Note that all references in the rejections below have been previously cited.

Affidavit

The affidavit submitted 6/5/2008 has been acknowledged.

Withdrawn Rejections

The following rejections or objection have been withdrawn due to the affidavit, claim amendments and cancellation:

1. Claim objection;

2. 35 USC 112, 2nd paragraph; and

3. 35 USC 112, 1st paragraph (Enablement).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 6, 8-21 and 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of increasing an immune response to an opportunistic infection comprising (in part) selecting an immunocompromised subject, administering to the subject an immunostimulatory D oligo (according to the formula of

claim 1), and evaluating the immune response to the secondary infection. Note that the oligo may be administered either *prior to* or after exposure of the secondary infection. It is not clear however, how one would be able to increase an immune response to an opportunistic infection or evaluate the immune response to the secondary infection if the immunocompromised subject has yet to be exposed to such an infection. Further, as claimed, it suggests that one would know what the identity of the secondary infection is prior to its infection in order to evaluate it. Claims 2, 4, 5, 6, 8-21 and 27-32 depend from claim 1.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 depends from cancelled claim 7.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6977245 (hereinafter as "Klinman et al").

Klinman discloses the use of "D type CpG oligodeoxynucleotides" and a method of using these ODNs to induce an immune response (see Abstract). Further, the sequences set forth by SEQ ID NO: 177 and SEQ ID NO: 1 of the instant application is

taught by SEQ ID NO: 1 of this prior art reference. These sequences include phosphodiester bases in both the CpG motif and its immediate flanking regions (see paragraph 94 and Table 1). Also see Table 1, for self-complementary sequences in bold. Infectious agents include viruses, bacteria and fungi (see paragraph 48) as well as Leishmania and hepatitis (see paragraph 135). Paragraph 129 describes administration of the ODN either alone or in combination with another molecule. While this reference does not describe any secondary infections, this reference meets the claims in administering the oligo to immunocompromised subjects *prior to* exposure to the secondary infection. With respect to an immunocompromised subject, the authors provide the following in paragraph 47: A disease or disorder in which the subject's immune system is not functioning in normal capacity or in which it would be useful to boost a subject's immune response. Immune system deficiencies include those diseases or disorders in which the immune system is not functioning at normal capacity, or in which it would be useful to boost the immune system response. In one specific, non-limiting example, a subject with an immune system deficiency has a tumor or cancer (e.g. tumors of the brain, lung (e.g. small cell and non-small cell), ovary, breast, prostate, colon, as well as other carcinomas and sarcomas). Thus, Klinman meet the limitations of the rejected claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-6, 9-22 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of Klinman et al (see above) and Fraternale et al (2000).

The teachings of Klinman et al fail to describe the following: the co-administration of HAART or AZT with an ODN for immunocompromised subjects. Note that Klinman does describe using his claimed oligos for immune system deficiencies which would include HIV or AIDS (human immunodeficiency virus or autoimmune disease syndrome). As discussed above, it would be useful to boost a subject's immune system with either HIV or AIDS particularly given potential exposure to secondary infections and

this would be obvious to the ordinary artisan. Also note that the teachings of Klinman et al characterize the responses to the oligos in all of the figures, including their activation of NK cells and PBMCs. It would have been obvious to one of ordinary skill in the art to potentiate an immune response by methods and oligos successfully described in the prior art for subjects with an immune deficiency and then evaluate the results to determine the success rate, particularly in immune deficient subjects exposed to some secondary infection.

Fraternale et al discuss the use of combination antiretroviral therapy in patients with HIV-1, including protease and reverse transcriptase inhibitors (see Abstract). This reference discloses that AZT is known for its anti-HIV-1 activity and has been shown to reduce progression of AIDS. Also, this reference teaches that HAART produces a decline in plasma virus to undetectable levels in many patients (see Discussion). Thus, it would have been obvious to one of ordinary skill in the art to combine either HAART or AZT with an ODN to further stimulate an immune response in a subject infected with HIV. One would have been motivated to do so, as suggest by Fraternale et al, because "patients entering these treatments are usually at advanced stages of the disease and have a poor immunologic status" (see page 219). There would have been a reasonable expectation of success given that the success of an ODN in eliciting immune responses against HIV is known as well as the success rate of both HAART and AZT in combating HIV. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648